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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, STATE OF CALIFORNIA, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF FLORIDA, STATE OF GEORGIA, STATE OF HAWAII, STATE OF ILLINOIS, STATE OF INDIANA, STATE OF LOUISIANA, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF MONTANA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF NEW YORK, STATE OF NORTH CAROLINA, STATE OF OKLAHOMA, STATE OF RHODE ISLAND, STATE OF TENNESSEE, STATE OF TEXAS, COMMONWEALTH OF VIRGINIA, and STATE OF WISCONSIN *ex rel.* JEAN BRASHER,

Plaintiffs,

v.

PENTEC HEALTH, INC.

Defendant.

Civil Action No. 13 5745

COMPLAINT AND JURY DEMAND

Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)

FILED
OCT 1 2013
MICHAEL E. KUNZ, Clerk
By Dep. Clerk

TABLE OF CONTENTS

Qui Tam Plaintiff / Relator Jean Brasher, by and through counsel, Kessler Topaz Meltzer & Check, LLP, on behalf of the United States of America, brings this Complaint against Defendant Pentec Health, Inc., and alleges based on direct and independent knowledge:

I. INTRODUCTION

1. This is an action to recover treble damages and civil penalties on behalf of the United States of America and the "Plaintiff States;" that is, the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia, all arising from false and fraudulent records, statements and claims made, used and caused to be made, used, and presented by Defendant Pentec Health, Inc., and / or its agents, employees, predecessors and co-conspirators, in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320-7b(b), the federal False Claims Act, 31 U.S.C. § 3729, *et seq.*, and the False Claims Acts of the respective Plaintiff States.

2. Defendant, a national specialty infusion services company, has since at least the commencement of the Medicare Part D program in 2006, systematically defrauded federally-funded health insurance programs, including Medicare and Medicaid and, upon information and belief, the Federal Employees Health Benefits Program ("FEHB") and the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS," now known as "TRICARE"), and health insurance programs funded by the Plaintiff States.

3. This scheme arises from Defendant Pentec's primary business of selling expensive, compounded infusion drugs, including infused pain medications and nutritional

supplements utilized in connection with Interdialytic Parenteral Nutrition ("IDPN") therapy, a mechanism of providing infused nutrition to renal dialysis patients.

4. In particular, Defendant Pentec knowingly and unlawfully induced beneficiaries of federally funded health care programs to utilize, and rewarded them for utilizing, Defendant Pentec's compounded pharmaceutical products. Defendant Pentec effectuated this scheme by paying kickbacks to patients through routine waiver of mandated federal and state program cost-sharing obligations – often in amounts exceeding several thousand dollars per beneficiary – without regard to authenticated financial need, and through the use of advertisement and solicitation. Defendant Pentec's scheme, in effect, locked federal health care program beneficiaries into only using Defendant Pentec's products, even where less costly alternatives existed, and stymied competition. As a result, claims submitted by Defendant Pentec to federal health care programs were false in that they were submitted in violation of the federal Anti-Kickback Statute.

5. Defendant Pentec's scheme further entailed reporting, and causing to be reported, false and fraudulent statements regarding the out-of-pocket expenditures paid by federal health care program beneficiaries. In so doing, upon information and belief, Defendant Pentec increased costs to the Medicare system, by hastening the point at which Medicare Part D beneficiaries emerged from the coverage gap and into catastrophic coverage, which is more costly to the Medicare program. Upon information and belief, Defendant Pentec's scheme further caused the federal government, in 2010, to send checks for $250 dollars to Medicare Part D beneficiaries who, unbeknownst to the federal government, were ineligible to receive this benefit because they had not, in fact, paid the cost-sharing obligations that entitled such relief.

6. Defendant Pentec further defrauded federal health care programs by submitting claims for services that were neither reasonable nor necessary based upon the clinical criteria established for infused nutritional therapy for end state renal disease patients.

II. JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over the claims brought under the False Claims Act pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. §§ 1331, 1345 and 1367. This Court has supplemental jurisdiction over the False Claims Act claims of the Plaintiff States pursuant to 28 U.S.C. § 1367(a) because those causes of action are so closely related to the claims within the Court's original jurisdiction that they form part of the same case or controversy under Article III of the Constitution. This federal court jurisdiction over state law false claims is further authorized by the federal False Claims Act itself, pursuant to 31 U.S.C. § 3732(b), as the federal and state claims arise from the same transactions and occurrences.

8. This Court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a) because Defendant Pentec is found, transacts business, and committed acts prohibited by 31 U.S.C. § 3729 in this District.

9. Venue lies in this District pursuant to 31 U.S.C. § 3732(a), and 28 U.S.C. §§ 1391(b) and 1391(c), because the acts proscribed by 31 U.S.C. § 3729 *et seq.*, and complained of herein, took place in part in this District and because the Defendant transacted business in this District.

10. In accordance with 31 U.S.C. § 3730(b)(2), this Complaint has been filed *in camera* and will remain under seal for a period of at least 60 days and shall not be served on the Defendant until the Court so orders.

11. Pursuant to 31 U.S.C. § 3730(b)(2), Relator has served copies of this Complaint upon the Honorable Zane D. Memeger, United States Attorney for the Eastern District of

Pennsylvania, and upon the Honorable Eric H. Holder, Attorney General of the United States of America.

12. This suit is not based upon prior public disclosures (31 U.S.C. § 3730(e)(4)(A) (2008 and 2010)) of allegations or transactions in a criminal, civil, or administrative hearing, lawsuit, or investigation, or in a Government Accounting Office or Auditor General's report, hearing, audit, or investigation, or from the news media.

13. To the extent that there has been a public disclosure, Relator is the original source of those allegations within the meaning of the False Claims Act. 31 U.S.C. § 3730(e)(4)(B) (2008 and 2010).

III. PARTIES

14. Plaintiff, the United States of America on behalf of its agency, the United States Department of Health and Human Services ("HHS") and its Centers for Medicare and Medicaid Services ("CMS), administers the Health Insurance Program for the Aged and Disabled established by Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq.* ("Medicare"), and Grants to States for Medical Assistance Programs pursuant to Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq.* ("Medicaid"), including the Medicare Prescription Drug Benefit, a voluntary prescription drug coverage plan for eligible individuals ("Medicare Part D"). *See* 42 U.S.C. §§ 1395w-101 *et seq.*; 42 C.F.R. Part 423.

15. Relator Jean Brasher is a resident of the State of California and a citizen of the United States. Relator Brasher has been employed in the field of medical billing and collection for more than twenty years. From in or around April 2011 to in or around February 2012, Relator Brasher was employed as a Medical Reimbursement Specialist in Defendant Pentec's Billing Department. In this capacity, Relator Brasher was responsible for analyzing, submitting, and reconciling claims for health care services provided by Defendant Pentec, including claims

submitted to Medicare, Medicaid, and other federally-funded health care programs. In the course of her employment, Relator Brasher became aware of the scheme set forth herein and the breadth of its operation throughout the United States.

16. Defendant Pentec Health Inc. ("Pentec") is a Pennsylvania corporation, headquartered in Boothwyn, Pennsylvania. Defendant Pentec is a national, privately held, specialty infusion services company that provides pharmaceutical products and clinical services to non-hospitalized patients. Defendant Pentec focuses much of its business on infusion therapies for patients suffering from chronic renal failure, chronic pain and spasticity.

17. A substantial part of Defendant Pentec's business was devoted to compounding and selling specialty infusion products; that is, physician prescribed medications and nutritional supplements administered to patients through intravenous or intraperitoneal means. In this capacity, Defendant Pentec operated as a specialty pharmacy. Upon information and belief, defendant Pentec maintained pharmacy licenses and sold its products in every state, and in the District of Columbia.

18. In general, specialty pharmacies are distinct from traditional pharmacies in that specialty pharmacies deliver medications requiring specialized handling, storage and distribution, often for patients with complex, chronic medical conditions, who require regular contact and disease management by practitioners. Specialty pharmacies sell specialty drugs, typically high-cost products utilized for certain therapies and requiring specialized administration.

19. At all times relevant to this Complaint, Defendant Pentec participated in federally funded health care programs by submitting claims for covered infusion products to federally-funded health care programs, including Medicare Part B, and Medicare Part D programs

managed by third-party entities. Upon information and belief, Defendant Pentec derived nearly half of its revenues from Medicare Part D claims in 2011, an amount of approximately $30 million from Part D claims alone.

IV. APPLICABLE LAW

A. Federal False Claims Act

20. The federal False Claims Act and the false claims acts of the respective Plaintiff States, although enacted at different times, pertain to the same subject matter. Accordingly, Relator relates these claims utilizing the terms of the federal False Claims Act. Moreover, the terms of the federal False Claims Act apply to all claims raised herein.

21. The federal False Claims Act provides, in pertinent part, that:

> Any person who . . . (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government a false or fraudulent claim for payment or approval;[1] [or] (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;[2]
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> is liable to the United States Government for a civil penalty of not less than [$5,500] and not more than [$11,000] [as amended] . . . plus three times the amount of damages which the Government sustains because of the act of that person.

22. For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information . . . (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of

[1] Effective May 20, 2009, this section was renumbered and amended to impose liability upon any person who "knowingly presents, or causes to be presented, false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A).

[2] Effective May 20, 2009, this section was renumbered and amended to impose liability upon any person who "knowingly makes, uses, or causes to be made or used, a false record of statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B).

the truth or falsity of the information, and no proof of specific intent to defraud is required. 31 U.S.C. § 3729(b)(1).

23. The term "claim" is defined to include "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property," that is made to contractors and agents of federal government programs. 31 U.S.C. § 3729(b)(2). The term "claim" includes claims submitted to third-party sponsors for drugs covered under Medicare Part D. *See United States ex rel. Spay v. CVS Caremark*, 913 F. Supp. 2d 125, 150 (E.D. Pa. 2012).

B. Anti-Kickback Statute

24. The federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(B) ("AKS"), prohibits offering to pay or paying any remuneration "to any person to induce such person to purchase . . . any good. . . service, or item for which payment may be made in whole or in part under a Federal healthcare program." *Id.*

25. Compliance with the AKS is expressly and impliedly required for reimbursement federal program claims, and claims made in violation of the law are actionable civilly under the False Claims Act. *See* 42 U.S.C. § 1320a-7b(g) (2010) (a "claim that includes items or services resulting from a violation of . . . [the AKS] constitutes a false or fraudulent claim for purposes of [the False Claims Act]. . . ."); *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295 (3d Cir. 2011).

V. FACTUAL ALLEGATIONS

A. Medicare and Medicaid

26. The United States, through HHS, administers the Medicare program, established by Title XVIII of the Social Security Act. *See* 42 U.S.C. §§ 1395 *et seq*. Medicare provides health insurance coverage for individuals over 65 years of age, individuals under 65 with certain

disabilities, and individuals of any age with End-Stage Renal Disease. In 2003, Congress passed the Medicare Prescription Drug Benefit, Improvement and Modernization Act, which established Medicare Part D, a voluntary prescription drug coverage benefit for eligible individuals. *See* 42 U.S.C. §§ 1395w-101 *et seq.*; 42 C.F.R. Part 423.

27. Medicare beneficiaries entitled to Medicare benefits under Medicare Part A (hospital insurance) or Medicare Part B (medical insurance) are eligible for prescription drug benefits under Part D, including those suffering from End Stage Renal Disease ("ESRD"). Drugs covered under the Part A or Part B benefit are not covered under Part D. 42 U.S.C. § 1396w-102(e)(2)(B). Notwithstanding the creation of the Part D benefit, certain prescription drugs remain covered under Medicare Part B, including, for example, most injectable and infused drugs administered by a licensed medical provider, as well as drugs infused through an infusion pump.

28. Medicaid is a public-assistance program that pays for medical expenses incurred by low-income patients. The Medicaid program pays for services pursuant to plans developed by the states and approved by the U.S. Department of Health and Human Services ("HHS") through CMS. *See* 42 U.S.C. §1396a(a)-(b). States pay doctors, hospitals, pharmacies, and other providers and suppliers of medical goods and services according to government-established rates. *See* 42 U.S.C. §1396b(a)(1), 1903(a)(1). The federal government then pays each state a statutorily determined percentage of "the total amount expended . . . as medical assistance under the State plan . . ." *See* 42 U.S.C. §1396b(a)(1).

29. Medicaid pays for outpatient prescription drugs on a per item basis, with claims submitted directly for billing and payment. Medicare Part B operates similarly. When a pharmacy fills a prescription, it transmits an electronic claim to the local administrator, which

then processes the claim and provides payment to the pharmacy. Medicare and Medicaid coverage regulations preclude coverage for items and services that are not "medically necessary." 42 U.S.C. § 1320c-5(a)(1).

B. Medicare Part D

30. Unlike coverage in Medicare Parts A and B, Part D coverage is not provided through the traditional Medicare program; instead, benefits are provided through private entities, known as "Plan Sponsors," who establish Part D benefit plans, with features that vary depending on certain factors. There exist many types of Part D plans, including stand-alone plans, plans offered in connection Medicare Advantage (Medicare Part C) plans, and plans that are employer or union sponsored and provide coverage to retirees. *See* 42 U.S.C. § 1395w-132; 42 C.F.R. § 423.4 (The federal government pays a Part D retirement subsidy for prescription drug coverage for these retiree plans.).

31. In order to obtain coverage under Part D, eligible Medicare beneficiaries must affirmatively elect enrollment in one of the hundreds of Part D plans offered by Plan Sponsors.

32. Plan Sponsors are required to submit the features of each Part D plan to CMS, which makes public the features of the plans, including the amount of applicable deductibles, co-insurance, co-payments and other potential out-of-pocket liabilities. 42 C.F.R. §§ 423.502, 423.265 and 423.272.

33. In order to qualify for Part D payments from CMS, each approved Plan Sponsor must submit, before each annual plan year, a certified bid for each offered plan. 42 C.F.R. § 423.265. The bid contains a monthly cost estimate for providing Part D benefits to an average Medicare beneficiary in a particular geographic area. Based upon the cost estimates, CMS calculates average regional and national cost estimates. 42 C.F.R. § 423.272(a)(2).

34. During each year, on a monthly basis, CMS pays the Plan Sponsor estimated payments comprised of the Sponsor's direct premium subsidy per enrolled, estimated reinsurance subsidies for catastrophic coverage, and estimated low-income subsidies. 42 C.F.R. §§ 423.315, 423.320.

35. Plan Sponsors notify CMS throughout the plan year each time a Medicare beneficiary has a prescription filled under Part D. Claims are submitted to CMS through a Prescription Drug Event ("PDE") record for every prescription that is filled for a plan member. By providing this drug cost and payment data for each filled prescription, the Plan Sponsor informs CMS of the actual prescription drug costs.

36. At the end of the plan year, if CMS has underpaid the sponsor for low-income subsidies or reinsurance costs, CMS makes up the difference. If CMS overpaid the sponsor for these costs, it recoups the overpayment from the Part D sponsor. 42 C.F.R. § 423.343.

37. After CMS reconciles a plan's low-income subsidy and reinsurance costs, it then determines risk-sharing amounts owed by the plan to CMS or by CMS to the plan related to the plan's direct subsidy bid. Risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs per beneficiary exceeded or fell below a target amount for the plan by certain threshold percentages (commonly called the Part D "risk corridor"). 42 U.S.C. § 1395w-115(e); 42 C.F.R. § 423.336.

C. Requirements of Medicare Part D Sponsors and Downstream Entities

38. Medicare requires that Part D Plan Sponsors agree to comply with the requirements and standards of Part D and all terms and conditions of payment. 42 U.S.C. § 1395w-112(b)(1); 42 C.F.R. § 423.505(i)(4)(iv). These terms include compliance with "[f]ederal laws and regulations designed to prevent fraud, waste and abuse, including . . . the False Claims Act . . .and the anti-kickback statute . . . . " 42 C.F.R. § 423.505(h)(1).

39. Further, the contract between the Part D Plan Sponsor and CMS must include those terms set forth in 42 C.F.R. § 423.505(b), including compliance with certain reporting requirements (*see* § 423.514) and claims submission (*see* § 423.505(b)(8) and (9)).

40. Compliance with regulatory requirements is similarly required of "downstream entities," typically those entities that maintain a contract with the Part D Sponsor to provide the ultimate health care service rendered to the enrollee. *See Medicare Prescription Drug Benefit Manual*, ch. 9, § 40. Under CMS regulations, Sponsors' subcontracts with pharmacies must contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. §§ 423.505(i)(3)(v) and 423.505(i)(4)(iv).

D. Submission of Claims by Specialty Pharmacies to Medicare Part D

41. When a specialty pharmacy receives a prescription from a physician, the pharmacy confirms Part D coverage and plan details for the beneficiary, and dispenses the prescribed drugs to or for the benefit of the Medicare Part D beneficiary. The pharmacy then submits an electronic claim to the beneficiary's Part D Plan Sponsor (either directly or through a subcontracted intermediary). This electronic claim includes the cost of the drug, a dispensing fee, and any sales or similar taxes paid, less any payments received from the enrollee. As a condition of payment, sponsors, in turn, must submit data and information necessary for CMS to effectuate Part D's payment provisions; this data includes the claims information provided by the specialty pharmacy to the Plan Sponsor for use in submitting PDE's to CMS. 42 C.F.R. § 1395w-115(c)(1)(C), (d)(2); 42 C.F.R. § 423.322.

42. The pharmacy then receives payment from the Plan Sponsor for the costs not paid by the beneficiary. The pharmacy is responsible for collecting any cost-sharing portion from the Part D beneficiary,

43. The Part D Plan Sponsor, in turn, notifies CMS that a drug has been purchased and dispensed, by completing a Prescription Drug Event ("PDE") record, which details the amount paid to the pharmacy. As a condition of payment, the information must be certified to CMS by the Sponsor as accurate, complete and truthful. 42 C.F.R. § 423.505(k)(1). In making this certification to CMS, the Sponsor relies upon the accuracy and integrity of the underlying claim information. 42 C.F.R. § 423.505(k)(3). CMS utilizes the information in the PDE at the end of the payment year to reconcile actual sponsor costs with advanced payments that have been made to the sponsor by CMS. *See United States ex rel. Spay v. CVS Caremark*, 913 F. Supp. 2d 125, 150 (E.D. Pa. 2012). These requirements are plainly summarized in CMS' *Medicare Prescription Drug Benefit Manual*, ch. 9, § 80.1:

> When submitting claims data to CMS for payment, Sponsors and their subcontractors must certify that the claims data is true and accurate to the best of their knowledge and belief. The False Claims Act is enforced against <u>any individual / entity</u> that knowingly submits (or causes another individual / entity to submit) a false claim for payment to the Federal government.

Id. (emphasis added).

44. Not all drugs, however, are eligible for reimbursement under Part D; instead, Part D plans only cover drugs prescribed for a "medically accepted indication that facilitates the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . . ." *Medicare Prescription Drug Benefit Manual*, ch. 6, § 10.6; *see* 42 U.S.C. § 1395w-102(e)(1); 42 C.F.R. § 423.100.

E. <u>Financial Responsibility of Medicare and Medicaid Enrollees</u>

45. Federally funded health care programs utilize beneficiary cost-sharing measures that impose financial responsibility on the beneficiary for certain costs related to the services utilized. For prescription drugs covered under Part B, the beneficiary is typically responsible for 20% of the Medicare-approved amount, as well as the applicable Part B deductible. States have

the option to establish out of pocket spending requirements for prescription drugs, which may include copayments, coinsurance, deductibles and other similar charges paid by the Medicaid enrollee.

46. Although the specific features may vary depending on the particular plan, Part D drug plans provide coverage in phases, with the amount of enrollee cost-sharing varying greatly depending on the phases of coverage. Coverage phases are determine by the amount of "true out-of-pocket" ("TrOOP") expenditures the enrollee has incurred on prescription medication during the calendar year.

47. Once an eligible enrollee selects a Part D plan, the enrollee begins paying monthly premiums to the Plan Sponsor, in accordance with the terms of the particular plan. When an enrollee obtains a prescription from a physician, the enrollee has the prescription filled by a pharmacy. The pharmacy confirms Part D coverage for the enrollee, as well as the amount of enrollee financial responsibility for the prescription.

48. Beyond the monthly premium, Part D coverage requires that beneficiaries maintain financial responsibility (also known as "cost-sharing") for:

a. an annual deductible;

b. a percentage-based coinsurance for actual costs above the annual deductible but at or below an initial coverage limit ("initial benefit");

c. one hundred percent of an amount above the deductible plus the coinsurance (this feature of Part D plans is commonly referred to as the "coverage gap" or "doughnut hole"); and

d. a percentage of catastrophic coverage ("Catastrophic Coverage") costs for the remainder of a coverage year once an enrollee's costs exceed the annual out-of-pocket threshold.

Sponsors maintain some degree of flexibility to offer plans that reduce cost-sharing obligations. *See Medicare Prescription Drug Benefit Manual*, ch. 5, § 20.3.

49. While, the amount of the annual deductible, initial coverage limit, out-of-pocket threshold and beneficiary cost-sharing are adjusted annually, 42 C.F.R. § 423.104(d)(5)(iv), during the period of 2006 to 2012, the out-of-pocket amount incurred by those on standard Part D plans ranged from approximately $3,600 to $4,700.

50. There is no cap on the amount of coverage beneficiary can receive under Catastrophic Coverage through the calendar year. Once the calendar year ends, however, the stages are reset and the beneficiary is once again responsible for the amounts correlating to the TrOOP stage.

51. Medicare additionally provides "Extra Help" benefit to pay prescription drug costs for those who meet specific income and resource limits. This benefit helps defray the cost of the monthly Part D premium, as well as other Part D out-of-pocket costs.

52. The following represents an example of the financial responsibility of an enrollee in a standard Part D plan during 2010:

a. After enrolling in a Part D plan, the beneficiary paid an out-of-pocket deductible for the first $310 of incurred prescription drug costs.

b. After paying this amount, the enrollee entered the second phase, and paid 25% of the incurred costs, with the plan paying 75%, up to the initial

coverage limit of $2,830. At this stage, the beneficiary has paid a total of $940 in out-of-pocket expenditures.

c. After expending this amount, the coverage gap required the beneficiary to pay 100% of the cost of prescription drugs up to the out-of-pocket limit of $4,550 (representing $6,440 in total spending on covered Part D drugs).

d. The enrollee then became eligible for Catastrophic Coverage, at which point the Part D plan covered 95% of the costs and the beneficiary paid 5%.

53. The correct calculation of TrOOP expenditures is an essential component of Part D plan administration and CMS has issued significant guidance on the TrOOP methodology, emphasizing the importance of accurate TrOOP reporting. *See*, *e.g.*, *Medicare Prescription Drug Benefit Manual*, ch. 5, § 30. As with other aspects of the Part D program, responsibility accurate reporting of TrOOP data to CMS falls upon the Part D Sponsor and downstream entities, including pharmacies. Indeed, PDE's specifically require the reporting of patient payments, listing the dollar amount paid by the Part D beneficiary.

54. Further, CMS has specifically identified inaccurate TrOOP calculation as an example of potential fraud, waste and abuse in the Medicare Part D program. *Medicare Prescription Drug Benefit Manual*, ch. 9, § 70.1.

F. Waivers of Cost-Sharing Obligations

55. It is well established that routine waivers of patient cost-sharing amounts, without regard to authenticated financial need, may constitute illegal remuneration under the Anti Kickback Statute. Indeed, as early as 1994, the HHS Office of Inspector General issued a "Special Fraud Alert" regarding the unlawful practice of routinely waiving cost-sharing amounts to be paid by Medicare beneficiaries, because such practices can result in illegal inducements to

beneficiaries and overutilization of healthcare items and services, in violation of the health care Anti-Kickback Statute. 59 Fed. Red. 65373, 65374 (Dec. 19, 1994); *see* 42 U.S.C. § 1320a-7b(b). In identifying common patterns of fraudulent conduct, the OIG specifically listed marketing tactics stating, "Insurance Accepted as Payment in Full," and the routine use of "financial hardship" forms with no good faith attempt to determine the beneficiary's financial condition. 59 Fed. Red. 65373, 65374 (Dec. 19, 1994).

56. The same principles embodied in the Special Fraud Alert have been applied in fashioning narrow statutory safe harbors that only permit waiver of cost-sharing obligations in extremely narrow circumstances, deemed to alleviate concerns of fraudulent inducements. Specifically, with regard to Medicare Part D programs, pharmacies may receive safe harbor protection under the AKS for waivers of cost-sharing amounts, only where the person making the waiver (i) does not offer the waiver as part of any advertisement or solicitation; (ii) does not routinely waive coinsurance or deductible amounts; and (iii) determines in good faith that the recipient of the waiver is in financial need or fails to collect the owed amount after reasonable collection efforts. 42 U.S.C. § 1320a-7b(b)(3)(G).

57. Similarly, the Medicare Prescription Drug Benefit Manual states that pharmacies may waive Part D cost-sharing amounts only "in an unadvertised, non-routine manner after determining that the beneficiary is financially needy or after failing to collect the cost-sharing amount despite reasonable efforts." *Medicare Prescription Drug Benefit Manual*, ch. 5, § 30.4. Routine waivers and reductions of cost-sharing amounts are only permitted for those Part D beneficiaries who receive Part D low-income subsidies; yet, even this exception is negated if the pharmacy "advertise[s] in any way the availability of waivers or cost reductions." *Id.*

G. IDPN Therapy

58. Healthy kidneys maintain the body's internal equilibrium of water and minerals, cleaning the blood by removing excess fluid, minerals and wastes. When kidneys fail, harmful wastes accumulate in the body, blood pressure may rise, the body may retain excess fluid, and the body may not produce sufficient blood cells.

59. End Stage Renal Disease ("ESRD") is a medical condition where the kidneys stop working such that the patient cannot survive without either dialysis or kidney transplant, as the kidneys are no longer capable of adequately removing waste from the blood.

60. Dialysis is a treatment for ESRD that cleans the blood by removing harmful waste, extra salt and excess fluids that build up in the blood. Two types of dialysis are commonly used to treat ESRD: hemodialysis and pertioneal dialysis.

61. With hemodialysis, a dialysis machine draws the patient's blood from the body through a special filter known as a dialyzer, which contains a cleansing solution known as dialysate to remove wastes and extra fluids. Once cleaned, the blood is then returned to the body. Hemodialysis is commonly administered to ESRD patients three times per week, with each dialysis session lasting approximately four hours. Hemodialysis may be provided in a hospital setting, outpatient setting, dialysis facility, or at home.

62. With peritoneal dialysis, a catheter is surgically placed in the abdomen; dialysate is introduced through the catheter with the patient's peritoneum (lining of the abdominal cavity) acting as a membrane across which fluids and wastes are exchanged from the blood.

63. Patients with ESRD on chronic hemodialysis commonly experience protein-calorie malnutrition. Protein calorie malnutrition is typically assessed by measurements of serum albumin.

64. Interdialytic Parenteral Nutrition ("IDPN") is a treatment designed to remedy malnutrition by infusing a solution of nutrients, such as amino acids, glucose and lipids ("IDPN Solution"), while the patient is receiving hemodialysis. IDPN therapy requires a physician order and prescription. The content of the IDPN Solution can be adjusted to meet to the specific nutritional needs of a given patient. Because IDPN is administered during hemodialysis, it does not require additional vascular access.

65. Where a patient is receiving peritoneal dialysis, IDPN Solution is infused into the peritoneal cavity. This is sometimes referred to as Intraperitoneal Parenteral Nutrition ("IPN").

66. Medicare and Medicaid cover IPDN and IPN (collectively referred, herein, as "IDPN") services for ESRD patients.

H. Defendant Pentec's Specialty Pharmacy Business

67. As part of its specialty pharmacy business, Defendant Pentec compounded and sold pain medication for infusion through pumps, and IDPN Solution, including Proplete-branded products ("Proplete"), an IDPN formula that was custom-compounded by Defendant Pentec according to the specific needs of the dialysis patient.

68. With regard to Medicare Part D claims, Pentec produced, distributed and billed for IDPN in the following manner:

a. Physicians wrote prescriptions for Pentec to provide compounded drugs. The prescriptions were transmitted to Defendant Pentec's pharmacy department.

b. Pentec employees verified that a particular patient maintained insurance coverage (including coverage by federally-funded health care programs), as well as the extent of coverage benefits.

c. The pharmacist compounded the ingredients necessary to create the proper formulation to address the patient's medical requirements.

d. Based upon the pharmacists' compounding, Pentec employees created an invoice for the therapy, which was entered into Defendant Pentec's CPR+ computer system. The invoice detailed the types and amounts of products needed to complete the prescription.

e. Defendant Pentec shipped the compounded solution to the appropriate recipient (frequently a dialysis center in which the IDPN treatment was being performed concurrently with hemodialysis). For IDPN Solution, shipments typically included a two week supply consisting of six, separate IDPN treatments.

f. Thereafter, a Pentec billing employee submitted an electronic claim to the federal program, either directly (for Medicare Part B and Medicaid), or to the Part D Sponsor, based upon the invoice.

g. Plan Sponsors processed the electronic claim and electronically submitted payment to Pentec for the claim, and provided Defendant Pentec with an Explanation of Benefits, which included information delineating the patient's cost-sharing obligation.

h. When Defendant Pentec received payments, the payment information was populated into the CPR+ system. When payments received were less than the total billable amount contained in the CPR+ system, a balance was recorded on the patient account.

i. Defendant Pentec divided balances into two categories: (i) balances evidencing an amount owed by an insurance company (including Medicare, Medicaid and Part D Sponsors) (hereinafter "Insurance Balances"); and (ii) balances evidencing a liability borne by a patient (hereinafter "Patient Balances").

j. Balances were forwarded to Relator (and to other employees responsible for collections) through a computerized queue in the CPR+ system. With regard to Insurance Balances, collectors contacted payors (including Part D Sponsors) to determine the reason for the balance and to attempt to obtain payment in full.

69. Upon information and belief, Part D claims for IDPN Solution averaged between approximately $3,000 and $4,000 per two week supply.

70. With regard to Medicare Part B and Medicaid, Pentec billed for covered compounded dugs by submitting claims directly to federal health care programs (or to their designated intermediaries).

I. Defendant Pentec's Policies

71. Defendant Pentec maintained policies specifically addressing and prohibiting conduct in violation of the federal Anti-Kickback Statute, including as related to the routine waiver of patient cost-sharing obligations. Notwithstanding these policies, Defendant Pentec knowingly and systematically flouted its own internal compliance measures.

72. For example, Pentec Policy and Procedure No. 9.11, "Accounts Receivable Co-Pay and Deductible Collection Policy" stated:

> *Pentech [sic] will invoice and collect co-pays and / or deductibles from each patient where there is a balance due from transactions involving amounts not payable by their*

insurance company based on Pentec's contract with the insurance company.

* * *

Pentec's policy is to bill for all applicable out-of-pocket amounts to patients' covered by insurance plans that are contracted with Pentech [sic] and to make reasonable efforts to collect such amounts.

* * *

Under no circumstances will Pentech [sic] engage in any of the following activities with respect to coinsurance and deductibles:

* * *

Advertise or market to the general public that patients will incur no out-of-pocket expenses.

Routinely use financial hardship as a reason to adjust or write-off coinsurance and deductible amounts.

J. Defendant Pentec's Fraudulent Schemes

73. Defendant Pentec operated a company-wide scheme to defraud federal and state healthcare programs by paying kickbacks to patients to induce the purchase of Defendant Pentec's compounded drugs. Upon information and belief, these kickbacks frequently exceeded thousands of dollars, per patient.

74. The AKS prohibits payments of kickbacks in connection with drugs and other goods and services covered by Medicare and Medicaid. Defendant Pentec's unlawful kickback scheme caused and had the potential to cause the very harms sought to be prevented by the AKS and its corresponding regulations and policies; specifically, (i) inducing beneficiaries to select Pentec's compounded drugs because of thousands of dollars in waived costs that beneficiaries would otherwise have to pay in connection with their federal health care program cost-sharing obligations; (ii) engaging in anti-competitive business practices that, in effect, corruptly locked

patients into purchasing Defendant Pentec's products, even where other cheaper and more effective products may have been available, and otherwise created an inequitable marketplace for competitors who elected not to engage in unlawful patient kickbacks; and, (iii) promoting overutilization of Defendant Pentec products by eliminating the cost-sharing provisions incorporated into federal health care programs. Defendant Pentec further defrauded federally funded health care programs by submitting, and causing to be submitted, false and fraudulent TrOOP calculations, resulting in overspending by federal programs.

75. By routinely waiving cost-sharing amounts (often through solicitation), without regard to individual circumstances and without *bona fide* authentication of patient financial needs, in exchange for patients' purchase of IDPN Solution, Defendant Pentec knowingly violated the AKS. Accordingly, all claims for payment submitted to federal health care programs by Defendant Pentec for patients having received these illegal kickbacks are false claims under the federal False Claims Act, and the correlating false claims acts of the Plaintiff States.

76. In or around March 2011, Relator Brasher interviewed for a position at Defendant Pentec. During the interview, Relator Brasher was informed that Defendant Pentec required assistance collecting money from patients and that substantial amounts of money had never been collected from patients.

77. In or around April 2011, Relator Brasher was hired by Pentec as a Reimbursement Specialist, assigned, primarily, to collect Insurance Balances.

78. As part of her regular employment, Relator maintained full access to the CPR+ system and all Defendant Pentec patient accounts, including access to records pertaining to events that preceded Relator's employment at Defendant Pentec. Defendant Pentec maintained

all billing and clinical information in the CPR+ computer application, a software system designed specifically for use by specialty pharmacies. The CPR+ system contained tabs that categorized various types of information related to a specific patient's account. With regard to collections information, the CPR+ system contained an online ledger of payments related to a specific patient account in a "patient payment" tab, which indicated the amount of money the patient had paid toward the overall balance.

79. Shortly after commencing her employment at Defendant Pentec, Relator conducted routine reviews of accounts in CPR+ per her job responsibilities. Relator noticed that an unusually high number of patient accounts had Patient Balances, or that Patient Balances had been written off based upon purported financial hardship of the patient. This was denoted with the term "FH" in the CPR+ column for "adjustments." The accounts reviewed by Relator pertained to claims that had already been submitted for payment by Defendant Pentec, including for reimbursement by Medicare Part B and D programs, with payment having been received (at least in part) by Defendant Pentec.

80. Thereafter, Relator brought her concerns to the billing and collections supervisor, JM, by telling JM that there were a high number of financial hardship write-offs, often without documentation establishing the purported hardship. JM responded by stating that was the way things were done at Pentec. Relator Brasher was instructed by JM to continue with her job collecting Insurance Balances.

81. Relator abided with the directive of her supervisor, but continued to recognize that high percentages of patient accounts either had uncollected Patient Balances or financial hardship waivers of Patient Balances. Accounts reviewed by Relator pertained to claims that had already been submitted for payment by Defendant Pentec, including for reimbursement by

Medicare Part B and D programs, with payment having been received (at least in part) by Defendant Pentec.

82. Relator spoke, again, with JM and again reported her concerns, including that routine waivers of cost-sharing amounts were not proper. JM responded by shrugging her shoulders and stating, in substance and in part, that Defendant Pentec could do whatever it wanted. Relator was instructed by JM to continue with her job collecting Insurance Balances.

83. Relator returned to her work and continued to examine patient accounts through the CPR+ system. Relator continued to identify that an extremely high percentage of Pentec patients had financial hardship write-offs on their accounts, often without any documentation purporting to establish financial need, or had Patient Balances. Relator identified individual Patient Balances of up to, approximately, $30,000.

84. The accounts reviewed by Relator pertained to claims that had already been submitted for payment by Defendant Pentec, including for reimbursement by Medicare Part B and D programs, with payment having been received (at least in part) by Defendant Pentec.

85. Relator continued to raise her concerns with JM.

86. Relator forwarded accounts with Patient Balances to another Pentec employee, DD, who was, in part, ostensibly responsible for collecting Patient Balances. Shortly after providing accounts to DD which had substantial Patient Balances, Relator would re-evaluate the patient account in the CPR+ system. Often, the Patient Balance had been written off as a financial hardship adjustment, thereby eliminating the patient's cost-sharing responsibility from the CPR+ system. Relator continued to raise concerns about Pentec's billing practices.

87. Subsequently, JM instructed Pentec employees on how to resolve accounts with uncollected balances. Specifically: (1) if there was a pre-existing FH waiver on the account, JM

instructed Relator and her colleagues to complete financial hardship adjustment forms again granting financial hardship waivers, without any authentication of actual financial need. The financial adjustment form was then submitted to JM, who would sign the form and submit the adjustment for posting in the CPR+ system; (2) if there was not a pre-existing FH waiver, JM instructed that the accounts were to be routed to the Patient Advocate, DD, who purportedly was assigned to validate financial hardship; in fact, DD continued to write-off patient cost-sharing amounts under FH.

88. Relator raised her concerns with JR, the Vice-President of Reimbursement. Shortly thereafter, Defendant Pentec required that adjustments in excess of $5,000 had to be presented to JR before being formally adjusted in the CPR+ system. Notwithstanding this change in procedure, when Relator reviewed accounts in the CPR+ system, it appeared that Patient Balances continued to be routinely waived.

89. Relator continued to raise her concerns about Defendant Pentec's billing practices, but was continually rebuffed by her management.

90. During her employment at Pentec, Relator was informed, by another Pentec employee, that Defendant Pentec's sales representatives were marketing, as an inducement, that patients' would not incur any out-of-pocket expenses should they elect to use Proplete for IDPN therapy; instead, patients were told, in substance and in part, that Defendant Pentec would accept 'insurance-only' as payment in full.

91. Relator further identified patient accounts in the CPR+ system where the requisite prescription had expired, but for which Pentec continued to ship compounded drugs and bill for those drugs. Relator identified these accounts to JM. When Relator examined the accounts in CPR+ within a few subsequent days, prescriptions were in the system and up to date. Relator

was able to determine that these prescriptions were backdated. Upon information and belief, when missing prescriptions were identified, Pentec employees would create backdated prescriptions to fill already-produced medications, and obtain signatures from the authorizing physician.

92. During her employment, Relator did not witness Defendant Pentec or its employees sending statements or invoices to patients indicating amounts owed to Defendant Pentec by patients for federal program cost-sharing (or for any other purpose).

93. Relator did not witness Defendant Pentec or its employees receiving payment from patients for cost-sharing (or any other) amounts.

94. Upon information and belief, Defendant Pentec did not invoice patients for Patient Balances and did not maintain a mechanism for collecting payments from patients.

95. By routinely waiving cost-sharing amounts in violation of federal law, Defendant Pentec, upon information and belief, caused false TrOOP accounting to be submitted to Part D Sponsors and to CMS. Upon information and belief, this, in turn, caused the federal Department of Health and Human Services to pay $250 coverage gap rebates to individuals who appeared eligible based upon falsely reported TrOOP information,[3] but who, in fact, had not made cost-sharing payments for Pentec's products, as a result of Defendant Pentec's scheme.

96. During Relator's employment at Pentec, JM explained to Relator the clinical indications that warranted use of Proplete IDPN therapy. Specifically, Relator was instructed that when a patient's albumin level exceeded a certain threshold, the patient no longer required Proplete because their nutritional state was sufficient to sustain the patient without the need for parenteral supplements.

[3] Section 1395w-152(c) of Title 42 provides for $250 "coverage gap rebates," on a one-time basis, for Part D beneficiaries whose cost-sharing obligations resulted in entering the 'doughnut hole' during 2010. *See* Health Care and Education Reconciliation Act of 2010, Section 1101.

97. Relator, however, identified several patient accounts that contained medical records indicating albumin levels that exceeded the threshold, but for whom Proplete continued to be administered on a weekly basis.

98. Relator discussed her concerns with JM about the submission of claims for medically unnecessary services. JM responded that it was administratively burdensome for Defendant Pentec (as well as the ordering physician) to remove patients from Proplete prescriptions and then resume treatment should the patient's nutritional state deteriorate. Accordingly, Defendant Pentec continued to provide and bill for Proplete notwithstanding the lack of clinical indication.

99. There was an individual (hereinafter "Witness 1"), who worked in Pentec's billing and reimbursement department. According to Witness 1, Defendant Pentec, through its pharmaceutical compounding program, double-billed federal health care programs for compounded drug ingredients.

100. Specifically, according to Witness 1, Defendant Pentec's pharmacists ordered large bags of covered compounding ingredients from pharmaceutical manufacturers in order to complete a compounding session for a specific patient. If excess drug ingredient remained from that compounding sessions, Defendant Pentec pooled and reused the wastage to fulfill another compounding order.

101. According to Witness 1, Defendant Pentec double-billed federal health care programs by billing for the entire compounding ingredient for the initial compounding session (including the wastage), but then submitting claims for a subsequent patient for whom the wastage had been used to fulfill that prescription. Thus, federal health care programs paid twice for the excess.

FIRST COUNT

VIOLATIONS OF FALSE CLAIMS ACT – PRESENTING FALSE CLAIMS [31 U.S.C. § 3729(a)(1) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(A)]

102. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

103. This is a claim for treble damages and civil penalties under Section 3729(a)(1) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(A), of the False Claims Act, 31 U.S.C. § 3729 *et seq*.

104. Defendant Pentec routinely waived patient cost-sharing amounts (often through solicitation), without regard to individual circumstances and without *bona fide* authentication of patient financial needs, which constitutes remuneration.

105. This remuneration was knowingly offered and paid to induce and reward the purchase of goods, items and services, paid by federal health care programs, including Medicare and Medicaid, from Defendant Pentec, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

106. Defendant Pentec's actions were not protected under "safe harbor" regulations.

107. As a prerequisite to participating in federally-funded health care programs, Defendant Pentec expressly certified (or, through its participation in a federally funded program, impliedly certified) its compliance with certain applicable statutes and regulations, including the federal Anti-Kickback Statute and other laws pertaining to fraud and abuse in federal healthcare programs.

108. As a result of the acts set forth above, Defendant knowingly presented, or caused to be presented, false or fraudulent claims to the United States Government for payment or

approval, in violation of Title 31, United States Code, Section 3729(a)(1) (2006), and, as amended, § 3729(a)(1)(A)

109. The United States, unaware of the false and fraudulent nature of these claims, paid these claims, which otherwise would not have been paid.

110. By reason of the false or fraudulent claims, the United States has sustained damages, and continues to sustain damages, in a substantial amount.

SECOND COUNT

VIOLATIONS OF FALSE CLAIMS ACT – USE OF FALSE STATEMENTS [31 U.S.C. § 3729(a)(2) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(B)]

111. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

112. This is a claim for treble damages and civil penalties under Section 3729(a)(2) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(B), of the False Claims Act, 31 U.S.C. § 3729 *et seq*.

113. Defendant Pentec knowingly made and used false records or statements, material to a false or fraudulent claim, by falsely representing the collection of patient cost-sharing amounts.

114. As a result of the acts set forth above, Defendant Pentec made and used, and caused others to make and use, false records or statements that were material to false or fraudulent claims for payment submitted to federal health care programs. The false records or statements included claims submitted to Part D Sponsors, Prescription Drug Event records, calculations of TrOOP spending amounts, and false certifications and representations of compliance with federal laws and regulations, including the federal Anti-Kickback Statute and federal False Claims Act.

115. As a result of the acts set forth above, Defendant knowingly presented, or caused to be presented, false or fraudulent claims to the United States Government for payment or approval, in violation of Title 31, United States Code, Section 3729(a)(1) (2006), and, as amended, § 3729(a)(1)(A).

116. The United States, unaware of the false and fraudulent nature of these claims, paid these claims, which otherwise would not have been paid.

117. The United State, unaware of the false and fraudulent nature of these claims, paid, in 2011, $250 rebates to Medicare Part D beneficiaries who were not entitled to such rebates.

118. By reason of the false or fraudulent claims, the United States has sustained damages, and continues to sustain damages, in a substantial amount.

THIRD COUNT

California False Claims Act
Cal. Gov't Code §§ 12650 – 12655

119. This is a claim for treble damages and civil penalties under the California False Claims Act, Cal. Gov't Code §§ 12650 – 12655. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

120. Defendant violated the California False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of California as described herein.

121. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of California.

122. The State of California, unaware of the false or fraudulent nature of these claims, paid such claims which the State of California would not otherwise have paid.

123. By reason of these payments, the State of California has been damaged, and continues to be damaged, in a substantial amount.

FOURTH COUNT

Colorado Medicaid False Claims Act
Col. Rev. Stat. §§ 25.5-4-303.5 – 25.5-4-309

124. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-303.5 – 25.5-4-309. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

125. Defendant violated the Colorado Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Colorado, as described herein.

126. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Colorado.

127. The State of Colorado, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Colorado would not otherwise have paid.

128. By reason of these payments, the State of Colorado has been damaged, and continues to be damaged, in a substantial amount.

FIFTH COUNT

Connecticut False Claims Act for Medical Assistance Programs
Conn. Gen. Stat. Ann. §§ 17b-301 *et seq.*

129. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act for Medical Assistance Programs, Conn. Gen. Stat. Ann. §§ 17b-301 *et seq*. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

130. Defendant violated the Connecticut False Claims Act for Medical Assistance Programs by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Connecticut, as described herein.

131. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Connecticut.

132. The State of Connecticut, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Connecticut would not otherwise have paid.

133. By reason of these payments, the State of Connecticut has been damaged, and continues to be damaged, in a substantial amount.

SIXTH COUNT

Delaware False Claims and Reporting Act
6 Del C §§ 1201(a)(1) and (2)

134. This is a claim for treble damages and civil penalties under the Delaware False Claims and Reporting Act, 6 Del C §§ 1201(a)(1) and (2). Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

135. Defendant violated the Delaware False Claims and Reporting Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Delaware, as described herein.

136. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Delaware.

137. The State of Delaware, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Delaware would not otherwise have paid.

138. By reason of these payments, the State of Delaware has been damaged, and continues to be damaged, in a substantial amount.

SEVENTH COUNT

District of Columbia Procurement Reform Amendment Act D.C. Code Ann. §§ 2-308.13 – 308.1526[4]

139. This is a claim for treble damages and civil penalties under District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §§ 2-308.13 – 308.1526. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

140. Defendant violated the District of Columbia Procurement Reform Amendment Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the District of Columbia, as described herein.

141. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the District of Columbia.

142. The District of Columbia, unaware of the false or fraudulent nature of these claims, paid such claims which the District of Columbia would not otherwise have paid.

143. By reason of these payments, the District of Columbia has been damaged, and continues to be damaged, in a substantial amount.

EIGHTH COUNT

Florida False Claims Act Fla. Stat. §§ 68.081 – 68.090

144. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. §§ 68.081 – 68.090. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

[4] Repealed effective April 8, 2011, and re-codified as D.C. Code Ann. § 2-381.01 *et seq.* without *qui tam* provisions.

145. Defendant violated the Florida False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Florida as described herein.

146. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Florida.

147. The State of Florida, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Florida would not otherwise have paid.

148. By reason of these payments, the State of Florida has been damaged, and continues to be damaged, in a substantial amount.

NINTH COUNT

Georgia State False Medicaid Claims Act
Ga. Code §§ 49-4-168 *et seq.*

149. This is a claim for treble damages and civil penalties under Georgia State False Medicaid Claims Act, Ga. Code §§ 49-4-168 *et seq*. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

150. Defendant violated the Georgia State False Medicaid Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Georgia, as described herein.

151. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Georgia.

152. The State of Georgia, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Georgia would not otherwise have paid.

153. By reason of these payments, the State of Georgia has been damaged, and continues to be damaged, in a substantial amount.

TENTH COUNT

Hawaii False Claims Acts
Haw. Rev. Stat. §§ 661-21 – 661-29

154. This is a claim for treble damages and civil penalties under the Hawaii False Claims Acts, Haw. Rev. Stat. §§ 661-21 – 661-29. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

155. Defendant violated the Hawaii False Claims Acts by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Hawaii, as described herein.

156. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Hawaii.

157. The State of Hawaii, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Hawaii would not otherwise have paid.

158. By reason of these payments, the State of Hawaii has been damaged, and continues to be damaged, in a substantial amount.

ELEVENTH COUNT

Illinois False Claims Act
740 Ill. Comp. Stat. 175/1 *et seq.*

159. This is a claim for treble damages and civil penalties under the Illinois False Claims Act, 740 Ill. Comp. Stat. 175/1 *et seq*. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

160. Defendant violated the Illinois False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Illinois, as described herein.

161. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Illinois.

162. The State of Illinois, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Illinois would not otherwise have paid.

163. By reason of these payments, the State of Illinois has been damaged, and continues to be damaged, in a substantial amount.

TWELFTH COUNT

Indiana False Claims and Whistleblowers Protection Act
Ind. Code Ann. §§ 5-11-5.5-1 – 5-11-5.5-18

164. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblowers Protection Act, Ind. Code Ann. §§ 5-11-5.5-1 – 5-11-5.5-18. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

165. Defendant violated the Indiana False Claims and Whistleblowers Protection Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Indiana, as described herein.

166. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Indiana.

167. The State of Indiana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Indiana would not otherwise have paid.

168. By reason of these payments, the State of Indiana has been damaged, and continues to be damaged, in a substantial amount.

THIRTEENTH COUNT

Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. §§ 46:437 *et seq.*

169. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §§ 46:437 *et seq*. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

170. Defendant violated the Louisiana Medical Assistance Programs Integrity Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Louisiana, as described herein.

171. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Louisiana.

172. The State of Louisiana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Louisiana would not otherwise have paid.

173. By reason of these payments, the State of Louisiana has been damaged, and continues to be damaged, in a substantial amount.

FOURTEENTH COUNT

Maryland False Health Claims Act of 2010
Md. Code Ann., Health-General §§ 2-601 *et seq.*

174. This is a claim for treble damages and civil penalties under the Maryland False Health Claims Act of 2010, Md. Code Ann., Health-General §§ 2-601 *et seq*. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

175. Defendant violated the Maryland False Health Claims Act of 2010 by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Maryland, as described herein.

176. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Maryland.

177. The State of Maryland, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Maryland would not otherwise have paid.

178. By reason of these payments, the State of Maryland has been damaged, and continues to be damaged, in a substantial amount.

FIFTEENTH COUNT

Massachusetts False Claims Law
Mass. Gen. Laws Ann. Ch. 12 §§ 5A *et seq.*

179. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Law, Mass. Gen. Laws Ann. Ch. 12 §§ 5A *et seq*. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

180. Defendant violated the Massachusetts False Claims Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the Commonwealth of Massachusetts, as described herein.

181. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth of Massachusetts.

182. The Commonwealth of Massachusetts, unaware of the false or fraudulent nature of these claims, paid such claims which the Commonwealth of Massachusetts would not otherwise have paid.

183. By reason of these payments, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in a substantial amount.

SIXTEENTH COUNT

Michigan Medicaid False Claims Act
Mich. Comp. Laws §§ 400.601 *et seq.*

184. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claims Act, Mich. Comp. Laws §§ 400.601 *et seq.* Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

185. Defendant violated the Michigan Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Michigan, as described herein.

186. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Michigan.

187. The State of Michigan, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Michigan would not otherwise have paid.

188. By reason of these payments, the State of Michigan has been damaged, and continues to be damaged, in a substantial amount.

SEVENTEENTH COUNT

Minnesota False Claims Act
Minn. Stat. §§ 15C.01 *et seq.*

189. This is a claim for treble damages and civil penalties under the Minnesota False Claims Act, Minn. Stat. §§ 15C.01 *et seq*. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

190. Defendant violated the Minnesota False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Minnesota, as described herein.

191. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Minnesota.

192. The State of Minnesota, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Minnesota would not otherwise have paid.

193. By reason of these payments, the State of Minnesota has been damaged, and continues to be damaged, in a substantial amount.

EIGHTEENTH COUNT

Montana False Claims Act
Mont. Code Ann. §§ 17-8-401 – 17-8-412

194. This is a claim for treble damages and civil penalties under Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 – 17-8-412. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

195. Defendant violated the Montana False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Montana, as described herein.

196. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Montana.

197. The State of Montana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Montana would not otherwise have paid.

198. By reason of these payments, the State of Montana has been damaged, and continues to be damaged, in a substantial amount.

NINETEENTH COUNT

Nevada Submission of False Claims to State or Local Government Act Nev. Rev. Stat. Ann. §§ 357.010 – 357.250

199. This is a claim for treble damages and civil penalties under the Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. §§ 357.010 – 357.250. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

200. Defendant violated the Nevada Submission of False Claims to State or Local Government Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Nevada, as described herein.

201. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Nevada.

202. The State of Nevada, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Nevada would not otherwise have paid.

203. By reason of these payments, the State of Nevada has been damaged, and continues to be damaged, in a substantial amount.

TWENTIETH COUNT

New Jersey False Claims Act
N.J. Stat. §§ 2A:32C-1 *et seq.*

204. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. §§ 2A:32C-1 *et seq*. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

205. Defendant violated the New Jersey False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Jersey, as described herein.

206. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Jersey.

207. The State of New Jersey, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Jersey would not otherwise have paid.

208. By reason of these payments, the State of New Jersey has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-FIRST COUNT

New Mexico Fraud Against Taxpayers False Claims Act
N.M. Stat. Ann. §§ 44-9-1 *et seq.*

209. This is a claim for treble damages and civil penalties under the New Mexico Fraud Against Taxpayers False Claims Act, N.M. Stat. Ann. §§ 44-9-1 *et seq*. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

210. Defendant violated the New Mexico Fraud Against Taxpayers False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Mexico, as described herein.

211. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Mexico.

212. The State of New Mexico, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Mexico would not otherwise have paid.

213. By reason of these payments, the State of New Mexico has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-SECOND COUNT

New York False Claims Act
N.Y. State Fin. Law §§ 187 *et seq.*

214. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. State Fin. Law §§ 187 *et seq*. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

215. Defendant violated the New York False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New York, as described herein.

216. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New York.

217. The State of New York, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New York would not otherwise have paid.

218. By reason of these payments, the State of New York has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-THIRD COUNT

North Carolina False Claims Act
N.C. Gen. Stat. §§ 1-605 *et seq.*

219. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, N.C. Gen. Stat. §§ 1-605 *et seq*. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

220. Defendant violated the North Carolina False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of North Carolina, as described herein.

221. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of North Carolina.

222. The State of North Carolina, unaware of the false or fraudulent nature of these claims, paid such claims which the State of North Carolina would not otherwise have paid.

223. By reason of these payments, the State of North Carolina has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-FOURTH COUNT

Oklahoma Medicaid False Claims Act
Okl. Stat. Title 63 §§ 5053 *et seq.*

224. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, Okl. Stat. Title 63 §§ 5053 *et seq*. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

225. Defendant violated the Oklahoma Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Oklahoma, as described herein.

226. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Oklahoma.

227. The State of Oklahoma, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Oklahoma would not otherwise have paid.

228. By reason of these payments, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-FIFTH COUNT

Rhode Island State False Claims Act
R.I. Gen. Laws §§ 9-1.1-1 *et seq.*

229. This is a claim for treble damages and civil penalties under the Rhode Island State False Claims Act, R.I. Gen. Laws §§ 9-1.1-1 *et seq*. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

230. Defendant violated the Rhode Island State False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Rhode Island, as described herein.

231. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Rhode Island.

232. The State of Rhode Island, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Rhode Island would not otherwise have paid.

233. By reason of these payments, the State of Rhode Island has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-SIXTH COUNT

Tennessee False Claims Act
Tenn. Code Ann. §§ 4-18-101 *et seq.*

234. This is a claim for treble damages and civil penalties under the Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 *et seq*. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

235. Defendant violated the Tennessee False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Tennessee, as described herein.

236. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Tennessee.

237. The State of Tennessee, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Tennessee would not otherwise have paid.

238. By reason of these payments, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-SEVENTH COUNT

Tennessee Medicaid False Claims Act
Tenn. Code. Ann. §§ 71-5-181 *et seq.*

239. This is a claim for treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code. Ann. §§ 71-5-181 *et seq*. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

240. Defendant violated the Tennessee Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Tennessee, as described herein.

241. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Tennessee.

242. The State of Tennessee, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Tennessee would not otherwise have paid.

243. By reason of these payments, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-EIGHTH COUNT

Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. §§ 36.001 – 36.132

244. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 – 36.132. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

245. Defendant violated the Texas Medicaid Fraud Prevention Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Texas, as described herein.

246. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Texas.

247. The State of Texas, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Texas would not otherwise have paid.

248. By reason of these payments, the State of Texas has been damaged, and continues to be damaged, in a substantial amount.

254. This is a claim for treble damages and civil penalties under the Wisconsin False

255. Defendant violated the Wisconsin False Claims for Medical Assistance Law, by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Wisconsin, as described herein.

256. As a result of the misconduct alleged herein, Defendant knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Wisconsin.

257. The State of Wisconsin, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Wisconsin would not otherwise have paid.

258. By reason of these payments, the State of Wisconsin has been damaged, and continues to be damaged, in a substantial amount.

WHEREFORE, Relator requests the following relief:

A. An Order requiring Defendant Pentec to cease violations of the federal False Claims Act, the false claims acts of the Plaintiff States, and the Anti-Kickback Statute;

B. An Order granting judgment against Defendant Pentec for three times the amount of damages the United States has sustained because of Defendant's actions, plus a civil penalty of $11,000 for each and every false claim that Defendant caused to be presented to the United States and / or its grantees;

C. An Order granting judgment against Defendant Pentec for three times the amount of damages each of the Plaintiff States has sustained because of Defendant's actions, plus the maximum authorized civil penalty for each and every false claim that Defendant caused to be presented to each of the Plaintiff States and / or its grantees;

D. An Order awarding to Relator the maximum amount allowed as a "Relator's Share" pursuant to 31 U.S.C. § 3730(d) of the federal False Claims Act, and under each of the statutes set forth above for the false claims acts of the Plaintiff States;

E. An Order awarding to Relator from Defendant Pentec all reasonable expenses that were necessarily incurred, plus reasonable attorneys' fees and costs; and,

F. An Order awarding to the United States, the Plaintiff States and Relator all such other relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff hereby demands a trial by jury as to all issues.

DATED, this 30th of September, 2013.

Respectfully submitted,

KESSLER TOPAZ
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By: _____

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